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I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

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Signed

Dated 9 December 2003

Patents Form 1/77

Patents Act 1977
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THE PATENT OFFICE
23 NOV 2002
NEWPORT

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25NOV02 E765815-3 000107
P01/7700 0.00-0227369.6

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference

GDM-MP100129-GB

2. Patent application number
(The Patent Office will fill in this part)

0227369.6

23 NOV 2002

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Tayside Flow Technologies Limited
Unit 20
Prospect Business Centre
Gemini Crescent Technology Park
Dundee Tayside DD2 1TY

Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation

UK

07979933002

4. Title of the invention

A HELICAL FORMATION FOR A CONDUIT

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Lloyd Wise, McNeight & Lawrence
Regent House, Heaton Lane
Stockport, Cheshire SK4 1BS

Patents ADP number *(if you know it)*

08458275001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

YES

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	4
Claim(s)	
Abstract	
Drawing(s)	3+3

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature: Lloyd Wise, McNeight & Lonsdale

Date: 21 November 2002

12. Name and daytime telephone number of person to contact in the United Kingdom: G D McCallum 0161 480 6394

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500505.

b) Write your answers in capital letters using black ink or you may type them.

c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.

d) If you have answered 'Yes' Patents Form 7/77 will need to be filed.

e) Once you have filled in the form you must remember to sign and date it.

f) For details of the fee and ways to pay please contact the Patent Office.

A Helical Formation for a Conduit

The invention relates to a helical formation for a conduit.

A number of documents have proposed using helical formations in conduits to encourage a desired flow pattern of a fluid within the conduit. Such helical formations have been proposed for a wide variety of applications, including pipelines and blood flow tubing. The purpose of the helical formations is generally to generate spiral flow of the fluid within the conduit to reduce turbulence and dead spots within the conduit.

Although the use of helical formations has been proposed as beneficial to fluid flow in conduits by helping to generate spiral fluid flow patterns, there is little or no information on the physical characteristics of the helical formation that is required to create a suitable spiral flow pattern. Clearly, some designs of helical formations will be ineffective at creating spiral flow and other will not create a beneficial spiral flow. For example, helical formations having a high helix angle may tend to create turbulence rather than spiral flow due.

In accordance with a first aspect of the present invention, there is provided a helical formation for a conduit, the helical formation comprising an elongate member defining at least a portion of a helix, the elongate member comprising an inwardly extending portion, the inwardly extending portion extending along the length of the elongate member and extending inwardly from the internal side walls of the conduit for a distance equal to between 10% and 80% of the distance from the longitudinal axis of the conduit to an internal side wall.

The terms "helical", "helix" and "spiral" as used herein cover the mathematical definition of helical and any combination of the mathematical definitions of helical and spiral.

Typically, the inwardly extending portion extends inwardly for a distance equal to between 40% and 70% of the distance from the longitudinal axis of the conduit to an internal side wall. Preferably, for a distance equal to between 40% and 60%,

more preferably, for a distance equal to between 45% and 55%. Most preferably, the inwardly extending portion extends inwardly for a distance equal to substantially 50% of the distance from the longitudinal axis of the conduit to an internal side wall. Where the conduit has a circular cross-section, the distance is as a percentage of the radius of the conduit.

The helical formation may be in the form of an insert adapted to be inserted into the conduit, in use. The insert may be removably inserted or may be permanently inserted.

Alternatively, the helical formation may be an integral part of a side wall of the conduit. For example, the helical formation may be formed by a deformation of a portion of the side wall of the conduit.

In one example of the invention, the helical formation may be for use in blood flow tubing for the human or animal body. The tubing may be synthetic or natural blood flow tubing. For example, the tubing may be a graft. In another example, the conduit may be a stent for insertion into blood flow tubing in the human or animal body.

The helical formation may comprise two or more inwardly extending formations, arranged in side-by-side relationship extending along the length of the elongate member.

Examples of a helical formation in accordance with the invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a stent having a first example of a helical formation;

Figure 2 is a cross-sectional view of the stent;

Figure 3 is a perspective view of an arterial graft having a second example of a helical formation; and

Figure 4 is a cross-sectional view of the graft.

Figures 1 and 2 show a stent 1 having a body section 10 with an internal surface 2 and a longitudinal axis 3. The body section 10 has a circular cross-section. The body section 10 typically, has a mesh construction and may be, for example a metallic mesh. The distance r from the longitudinal axis 3 to the internal surface 2 is the internal radius of the stent 1. Within the stent 1 is a helical formation in the form of an insert 4. The insert 4 is helically shaped and defines a helix around the longitudinal axis 3. The insert 4 comprises a base portion 5 and two inwardly extending fins 6, 7, which extend along the length of the insert 4. The insert 4 is generally formed from a biocompatible material, such as polyurethane and may be melted onto the mesh structure of the stent 1 so that the material of the stent 1 is entrained within the material of the insert 4.

Each of the fins 6, 7 extend by a height h from the internal surface 2. The height h of the fins 6, 7 is equal to 50% of the internal radius, r. That is, $h = r/2$.

Figures 3 and 4 show an arterial graft 20 for blood flow tubing for use in the human or animal body. The graft 20 comprises a body section 21 having an internal surface 22 and a longitudinal axis 23. The graft 20 has internal radius r from the longitudinal axis to the internal surface 22. The body section 21 is typically formed from a biocompatible material, such as woven or knitted polyester. A helical formation 24 is formed by a deformation of the side wall of the body section 21. The helical formation 24 extends inwardly by a height h from the internal surface 22 and extends along the length of the graft 20 to define a helix around the longitudinal axis 23.

In the graft 20, the height, h, of the helical formation 24 equals 50% of the internal radius, r. That is, $h = r/2$ for the graft 20.

The inventors have found that a height h equal to r/2 (or 50% of the radius) is particularly advantageous for generating spiral flow of blood within the stent 1 or the graft 20. They have also found that if the height h is too small, a negligible spiral flow pattern is produced by the insert 4 and the helical formation 24. In contrast, if the height h is too large relative to the internal radius r, the fins 6, 7 or

the helical formation 24 tend to obturate the stent 1 or graft 20, respectively, and have a restrictive effect on flow.

While a height h = r/2 has been found to be produce a desired spiral flow pattern of blood in blood flow tubing, such as grafts and stents, the inventors have also found that other helical formation heights also have advantages in promoting spiral flow patterns. Therefore, the height h of the helical formation is typically, between 10% and 80% of the internal radius r, preferably, between 20% and 70%, more preferably between 40% and 60% and most preferably between 45% and 55%.

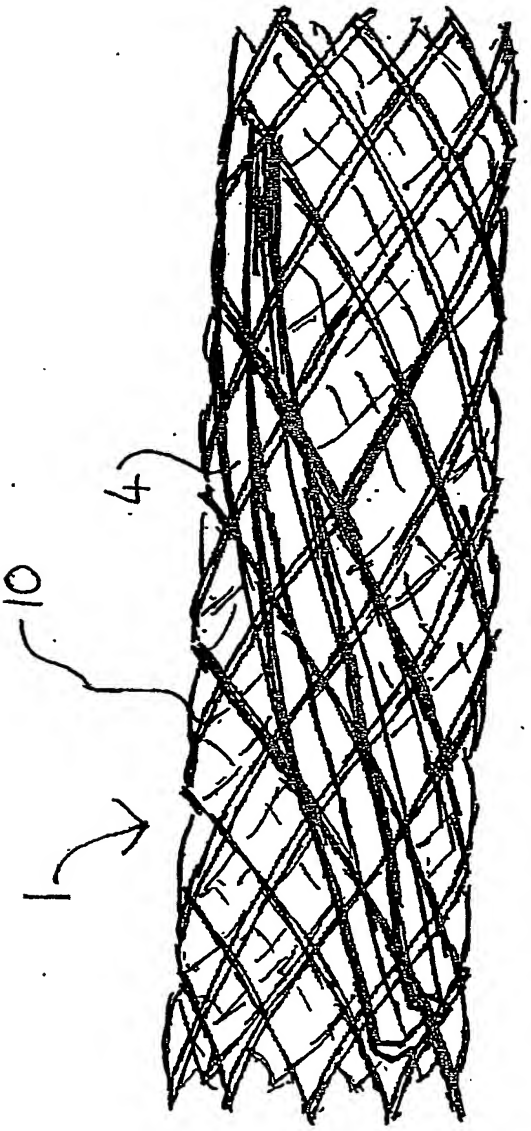

Figure 1

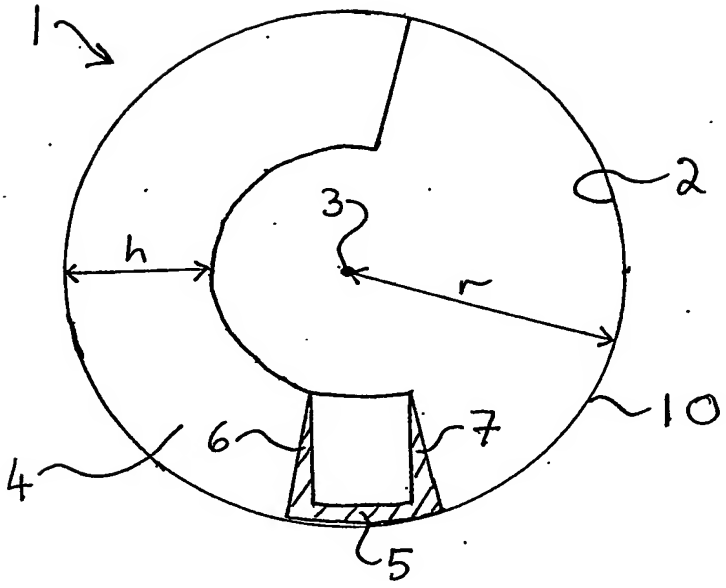

Figure 2

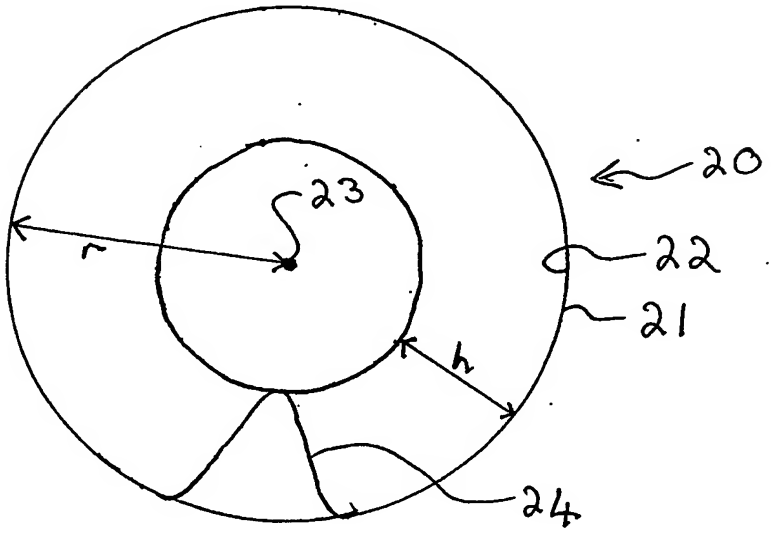

Figure 4

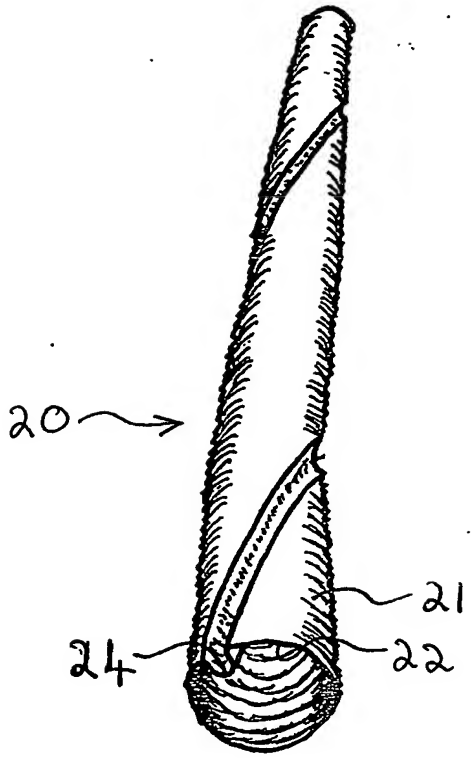

Figure 3